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10/668,767	09/23/2003	Steven Gutteridge	BB1533USNA	4390

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EXAMINER	
WHITEMAN, BRIAN A	

ART UNIT	PAPER NUMBER
1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/668,767	GUTTERIDGE ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-33 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-33 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, drawn to an isolated nucleotide fragment comprising a nucleic acid sequence encoding an amino acid sequence identity of at least 80% when compared to the polypeptide set forth in SEQ ID NO: 2, classifiable in class 536, subclass 23.1.

II. Claims 1-9, drawn to an isolated nucleotide fragment comprising a nucleic acid sequence encoding an amino acid sequence identity of at least 80% when compared to the polypeptide set forth in SEQ ID NO: 4, classifiable in class 536, subclass 23.1.

III. Claims 1-9, drawn to an isolated nucleotide fragment comprising a nucleic acid sequence encoding an amino acid sequence identity of at least 80% when compared to the polypeptide set forth in SEQ ID NO: 6, classifiable in class 536, subclass 23.1.

IV. Claims 1-9, drawn to an isolated nucleotide fragment comprising a nucleic acid sequence encoding an amino acid sequence identity of at least 80% when compared to the polypeptide set forth in SEQ ID NO: 8, classifiable in class 536, subclass 23.1.

V. Claims 1-9, drawn to an isolated nucleotide fragment comprising a nucleic acid sequence encoding an amino acid sequence identity of at least 80% when compared to the polypeptide set forth in SEQ ID NO: 128, classifiable in class 536, subclass 23.1.

VI. Claims 1-9, drawn to an isolated nucleotide fragment comprising a nucleic acid sequence encoding an amino acid sequence identity of at least 80% when compared to the polypeptide set forth in SEQ ID NO: 130, classifiable in class 536, subclass 23.1.

VII. Claims 1-9, drawn to an isolated nucleotide fragment comprising a nucleic acid sequence encoding an amino acid sequence identity of at least 80% when compared to the polypeptide set forth in SEQ ID NO: 144, classifiable in class 536, subclass 23.1.

VIII. Claims 1-9, drawn to an isolated nucleotide fragment comprising a nucleic acid sequence encoding an amino acid sequence identity of at least 80% when compared to the polypeptide set forth in SEQ ID NO: 146, classifiable in class 536, subclass 23.1.

IX. Claim 10, drawn to a method of comparing SEQ ID NO: 2, 4, 6, 8, 10, 128, 130, 144, and 146 and other ion channel and receptor sequences, classifiable in class 435, subclass 7.1.

X. Claims 11-15, drawn to an isolated polypeptide set forth in SEQ ID NO: 2, classifiable in class 530, subclass 350.

XI. Claims 11-15, drawn to an isolated polypeptide set forth in SEQ ID NO: 4, classifiable in class 530, subclass 350.

XII. Claims 11-15, drawn to an isolated polypeptide set forth in SEQ ID NO: 6, classifiable in class 530, subclass 350.

XIII. Claims 11-15, drawn to an isolated polypeptide set forth in SEQ ID NO: 8, classifiable in class 530, subclass 350.

XIV. Claims 11-15, drawn to an isolated polypeptide set forth in SEQ ID NO: 128, classifiable in class 530, subclass 350.

XV. Claims 11-15, drawn to an isolated polypeptide set forth in SEQ ID NO: 130, classifiable in class 530, subclass 350.

XVI. Claims 11-15, drawn to an isolated polypeptide set forth in SEQ ID NO: 144, classifiable in class 530, subclass 350.

XVII. Claims 11-15, drawn to an isolated polypeptide set forth in SEQ ID NO: 146, classifiable in class 530, subclass 350.

XVIII. Claim 16, drawn to a method of evaluating at least one compound for its ability to modulate calcium homeostasis, the method comprising transforming a host cell with a recombinant construct comprising a nucleotide sequence encoding the polypeptide set forth in SEQ ID NO: 2, classifiable in class 435, subclass 455.

XIX. Claim 16, drawn to a method of evaluating at least one compound for its ability to modulate calcium homeostasis, the method comprising transforming a host cell with a recombinant construct comprising a nucleotide sequence encoding the polypeptide set forth in SEQ ID NO: 4, classifiable in class 435, subclass 455.

XX. Claim 16, drawn to a method of evaluating at least one compound for its ability to modulate calcium homeostasis, the method comprising transforming a host cell with a recombinant construct comprising a nucleotide sequence encoding the polypeptide set forth in SEQ ID NO: 6, classifiable in class 435, subclass 455.

XXI. Claim 16, drawn to a method of evaluating at least one compound for its ability to modulate calcium homeostasis, the method comprising transforming a host cell with a recombinant construct comprising a nucleotide sequence encoding the polypeptide set forth in SEQ ID NO: 8, classifiable in class 435, subclass 455.

XXII. Claim 16, drawn to a method of evaluating at least one compound for its ability to modulate calcium homeostasis, the method comprising transforming a host cell with a recombinant construct comprising a nucleotide sequence encoding the polypeptide set forth in SEQ ID NO: 128, classifiable in class 435, subclass 455.

XXIII. Claim 16, drawn to a method of evaluating at least one compound for its ability to modulate calcium homeostasis, the method comprising transforming a host cell with a recombinant construct comprising a nucleotide sequence encoding the polypeptide set forth in SEQ ID NO: 130, classifiable in class 435, subclass 455.

XXIV. Claim 16, drawn to a method of evaluating at least one compound for it's ability to modulate calcium homeostasis, the method comprising transforming a host cell with a recombinant construct comprising a nucleotide sequence encoding the polypeptide set forth in SEQ ID NO: 144, classifiable in class 435, subclass 455.

XXV. Claim 16, drawn to a method of evaluating at least one compound for its ability to modulate calcium homeostasis, the method comprising transforming a host cell

with a recombinant construct comprising a nucleotide sequence encoding the polypeptide set forth in SEQ ID NO: 146, classifiable in class 435, subclass 455.

XXVI. Claims 16-18, drawn to a method of evaluating at least one compound which modulates ryanodine receptor activity, the method comprising contacting at least one compound with the polypeptide set forth in SEQ ID NO: 2, wherein the method is a ligand binding assay, classifiable in class 435, subclass 7.

XXVII. Claims 16-18, drawn to a method of evaluating at least one compound which modulates ryanodine receptor activity, the method comprising contacting at least one compound with the polypeptide set forth in SEQ ID NO: 4, wherein the method is a ligand binding assay, classifiable in class 435, subclass 7.1.

XXVIII. Claims 16-18, drawn to a method of evaluating at least one compound which modulates ryanodine receptor activity, the method comprising contacting at least one compound with the polypeptide set forth in SEQ ID NO: 6, wherein the method is a ligand binding assay, classifiable in class 435, subclass 7.1.

XXIX. Claims 16-18, drawn to a method of evaluating at least one compound which modulates ryanodine receptor activity, the method comprising contacting at least one compound with the polypeptide set forth in SEQ ID NO: 8, wherein the method is a ligand binding assay, classifiable in class 435, subclass 7.1.

XXX. Claims 16-18, drawn to a method of evaluating at least one compound which modulates ryanodine receptor activity, the method comprising contacting at least one compound with the polypeptide set forth in SEQ ID NO: 128, wherein the method is a ligand binding assay, classifiable in class 435, subclass 7.1.

XXXI. Claims 16-18, drawn to a method of evaluating at least one compound which modulates ryanodine receptor activity, the method comprising contacting at least one compound with the polypeptide set forth in SEQ ID NO: 130, wherein the method is a ligand binding assay, classifiable in class 435, subclass 7.1.

XXXII. Claims 16-18, drawn to a method of evaluating at least one compound which modulates ryanodine receptor activity, the method comprising contacting at least one compound with the polypeptide set forth in SEQ ID NO: 144, wherein the method is a ligand binding assay, classifiable in class 435, subclass 7.1.

XXXIII. Claims 16-18, drawn to a method of evaluating at least one compound which modulates ryanodine receptor activity, the method comprising contacting at least one compound with the polypeptide set forth in SEQ ID NO: 146, wherein the method is a ligand binding assay, classifiable in class 435, subclass 7.1.

XXXIV. Claims 16, 19, and 20, drawn to a method of evaluating at least one compound which modulates ryanodine receptor activity, the method comprising contacting at least one compound with the polypeptide set forth in SEQ ID NO: 2, classifiable in class 435, subclass 4.

XXXV. Claims 16, 19, and 20, drawn to a method of evaluating at least one compound which modulates ryanodine receptor activity, the method comprising contacting at least one compound with the polypeptide set forth in SEQ ID NO: 4, classifiable in class 435, subclass 4.

XXXVI. Claims 16, 19, and 20, drawn to a method of evaluating at least one compound which modulates ryanodine receptor activity, the method comprising contacting at

least one compound with the polypeptide set forth in SEQ ID NO: 6, classifiable in class 435, subclass 4.

XXXVII. Claims 16, 19, and 20, drawn to a method of evaluating at least one compound which modulates ryanodine receptor activity, the method comprising contacting at least one compound with the polypeptide set forth in SEQ ID NO: 8, classifiable in class 435, subclass 4.

XXXVIII. Claims 16, 19, and 20, drawn to a method of evaluating at least one compound which modulates ryanodine receptor activity, the method comprising contacting at least one compound with the polypeptide set forth in SEQ ID NO: 128, classifiable in class 435, subclass 4.

XXXIX. Claims 16, 19, and 20, drawn to a method of evaluating at least one compound which modulates ryanodine receptor activity, the method comprising contacting at least one compound with the polypeptide set forth in SEQ ID NO: 130, classifiable in class 435, subclass 4.

XXXX. Claim 16, 19, and 20, drawn to a method of evaluating at least one compound which modulates ryanodine receptor activity, the method comprising contacting at least one compound with the polypeptide set forth in SEQ ID NO: 144, classifiable in class 435, subclass 4.

XXXXI. Claims 16, 19, and 20, drawn to a method of evaluating at least one compound which modulates ryanodine receptor activity, the method comprising contacting at least one compound with the polypeptide set forth in SEQ ID NO: 146, classifiable in class 435, subclass 4.

XXXXII. Claim 21, drawn to an isolated nucleotide fragment encoding an insect ion channel comprising at least two polypeptide sequences set forth in any of SEQ ID NOs: 63-119 provided that said polypeptide sequences do not comprise any of SEQ ID NOs: 56, 120-126, classifiable in class 536, subclass 23.1.

XXXXIII. Claims 22 and 23, drawn to a method of identifying a nucleic acid sequence encoding an insect ion channel comprising: a) obtaining an isolated nucleic acid sequence encoding a first polypeptide having at least 100 amino acids; b) comparing the first polypeptide with a comparative polypeptide sequence selected from the group consisting of SEQ ID NOs: 63-119; and c) repeating step (b) with a different comparative polypeptide sequence wherein said different comparative polypeptide is selected from the group consisting of SEQ ID NOs: 63-119, classifiable in class 435, subclass 7.1.

XXXXIV. Claims 24-26, and 28, drawn to a method for expressing an isolated nucleic acid encoding a toxic insect ion channel using a recombinant construct comprising a promoter operably linked to a transcription termination nucleic acid fragment operably linked to a toxic insect ion channel nucleic acid, classifiable in class 435, subclass 455.

XXXXV. Claim 27, drawn to a method for expressing an isolated nucleic acid encoding a toxic insect ion channel using a recombinant construct comprising a promoter operably linked to an isolated nucleic acid encoding a toxic insect ion channel nucleic acid, wherein the isolated nucleic acid fragment also comprises an intron

which interferes with expression of the toxic insect ion channel, classifiable in class 435, subclass 455.

XXXXVI. Claims 29-32, drawn to a recombinant construct comprising a promoter operably linked to a transcription termination nucleic acid fragment operably linked to a toxic insect ion channel nucleic acid, classifiable in class 435, subclass 320.1.

XXXXVII. Claim 33, drawn to a recombinant construct comprising a promoter operably linked to an isolated nucleic acid encoding a toxic insect ion channel nucleic acid, wherein the isolated nucleic acid fragment also comprises an intron, which interferes with expression of the toxic insect ion channel, classifiable in class 435, subclass 320.1.

The inventions are distinct, each from the other because of the following reasons:

The isolated nucleotide fragments in Inventions I-VIII, the isolated polypeptides in Inventions X-XVII, the isolated nucleotide fragment in Invention XXXXII, and the constructs in Inventions XXXXVI and XXXXVII and are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because each product has a different function, different effect and different mode of operation. Additionally, polynucleotides and polypeptides can be used by materially different methods. Polynucleotides can be used as detection probes, polypeptides can be used for antigen presenting cell priming, and constructs can be used in *in vitro* gene expression assays. The constructs in Inventions XXXXVI-XXXXVII do not require

the isolated nucleotide fragments in Inventions I-VIII or invention XXXXII. The construct in Invention XXXXVI does not require the particulates of the construct in Invention XXXXVII. Furthermore, searching the inventions of Groups I-VIIII, X-XVII, XXXXII, XXXXVI, and XXXXVII together would impose a serious search burden. In the instant case, the search of the nucleotide fragments, polypeptides, constructs have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides, which would not have described the nucleotide fragments or constructs. Searching therefore is not coextensive.

Inventions I-VIII, XXXXII, XXXXVI, and XXXXVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are patentably distinct. The SEQ ID NO required in Inventions I-VIII are not required in Groups XXXXII, XXXXVI, and XXXXVII and vice versa. Furthermore, searching the inventions together would impose a serious search burden. In the instant case, the search of the nucleotide fragments and constructs have a separate status in the art as shown by their different classifications. Searching therefore is not coextensive. In addition, the isolated nucleic fragments include polynucleotides having less than 100% identity to the sequences identified. This search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature. The scope of claimed isolated nucleic fragments extend beyond the polynucleotides that encode the

claimed polypeptides. As such, it would be burdensome to search the inventions of groups I-VIII, XXXXII, XXXXVI, and XXXXVII together.

Inventions X-XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are patentably distinct. The SEQ ID NO required in Invention X is not require in Inventions XI-XVIII and vice-versa. Furthermore, searching the inventions together would impose a serious search burden. Searching therefore is not coextensive. As such, it would be burdensome to search the inventions of groups X-XVIII together.

Inventions I-VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant application does not disclose that the isolated nucleic acid fragment and method of isolating nucleic acid fragments are capable of use together. The method of Group IX does not require the nucleic acid sequence encoding SEQ ID NO: 2, 4, 6, 8, 128, 130, 144, or 146. Searching the inventions of I-VIII and IX together would impose a serious search burden. The inventions of Groups I-VIII and IX have a separate search status in the art as shown by their different classifications.

Inventions X-XVII and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case the isolated polypeptide in groups X-XVII can be used to make recombinant antibodies as opposed to its use in isolating nucleic acid fragments encoding ryanodine receptors and related polypeptides by using degenerate oligomers.

Searching the inventions of Groups X-XVII and IX together would impose serious search burden. The inventions X-XVII and IX have a separate search status in the art as shown by their different classifications. Moreover, in the instant case, the search for the isolated polypeptides and the method of isolating nucleic acid fragments are not coextensive. The search for group IX would require a text search for the method of isolating nucleic acid fragments in addition to a search of SEQ ID NO: 2, 4, 6, 8, 10, 128, 130, 144, and 146. Prior art that teaches that isolated polypeptides would not necessarily be applicable to the method of using the oligomers. Moreover, if the polypeptide product were known, the method of isolating nucleic fragments may be novel and unobvious in view of the preamble or active steps.

Inventions I-VIII and the method of Inventions XXVI-XXXXV are unrelated because the product of groups I-VIII is not used or other wise involved in the process of groups XXVI-XXXXV.

Inventions X-VII and the method of Inventions XVIII-XXV and XXXXII-XXXXV are unrelated because the product of groups X-VII is not used or other wise involved in the process of groups XVIII-XXV, XXXXII-XXXXV.

Inventions XXXXII, XXXXVI, and XXXXVII and the method of Inventions IX and XVIII-XXXXI are unrelated because the product of groups XXXXII, XXXXVI, and XXXXVII is not used or other wise involved in the process of groups IX and XVIII-XXXXI.

Inventions IX, XVIII-XXV, and XXXXIII-XXXXV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of isolating a nucleic acid fragment encoding ryanodine receptors and related polypeptides (group IX), a method for evaluating at least one compound for its ability to modulate calcium homeostasis using a recombinant construct comprising a distinct isolated nucleic acid fragment (groups XVIII-XXV), a method for identifying a nucleic acid encoding an insect ion channel (group XXXXIII), the method for expressing an isolated nucleic acid fragment encoding a toxic insect ion channel (group XXXXIV), and the method for expressing an isolated nucleic acid fragment encoding a toxic insect ion channel (group XXXXV) are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Therefore, each method is divergent in material and steps. For these reasons Inventions IX, XVIII-XXV, XXXXIII-XXXXV are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The Inventions of Groups IX, XVIII-XXV, XXXXIII-XXXXV have a separate search in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups IX, XVIII-XXV, XXXXIII-XXXXV together.

Inventions IX, XXVI-XXXIII, and XXXXIII-XXXXV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP §

808.01). The instant specification does not disclose that these methods would be used together. The method of isolating a nucleic acid fragment encoding ryanodine receptors and related polypeptides (group IX), a method for evaluating at least one compound for its ability to modulate calcium homeostasis using a recombinant construct comprising a distinct isolated nucleic acid fragment (groups XXVI-XXXIII), a method for identifying a nucleic acid encoding an insect ion channel (group XXXXIII), the method for expressing an isolated nucleic acid fragment encoding a toxic insect ion channel (group XXXXIV), and the method for expressing an isolated nucleic acid fragment encoding a toxic insect ion channel (group XXXXV) are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Therefore, each method is divergent in material and steps. For these reasons Inventions IX, XXVI-XXXIII, XXXXIII-XXXXV are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The Inventions of Groups IX, XXVI-XXXIII, XXXXIII-XXXXV have a separate search in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups IX, XXVI-XXXIII, XXXXIII-XXXXV together.

Inventions IX, XXXIV-XXXXI, and XXXXIII-XXXXV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of isolating a nucleic acid fragment encoding ryanodine receptors and related

polypeptides (group IX), a method for evaluating at least one compound for its ability to modulate calcium homeostasis using a recombinant construct comprising a distinct isolated nucleic acid fragment (groups XXXIV-XXXXI), a method for identifying a nucleic acid encoding an insect ion channel (group XXXXIII), the method for expressing an isolated nucleic acid fragment encoding a toxic insect ion channel (group XXXXIV), and the method for expressing an isolated nucleic acid fragment encoding a toxic insect ion channel (group XXXXV) are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Therefore, each method is divergent in material and steps. For these reasons Inventions IX, XXXIV-XXXXI XXXXIII-XXXXV are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The Inventions of Groups IX, XXXIV-XXXXI, XXXXIII-XXXXV have a separate search in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups IX, XXXIV-XXXXI, XXXXIII-XXXXV together.

Inventions X and XVIII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination can use a nucleic acid sequence encoding an amino acid sequence of at least 80% when compared to a polypeptide consisting of SEQ ID NO: 2 or a

polypeptide consisting of SEQ ID NO: 2. The subcombination has separate utility such as a method for evaluating at least one compound for its ability to modulate calcium homeostasis.

The reasons set forth above applies to each subcombination set forth in groups XI-XVII and their corresponding combination as set forth in groups XIX-XXV.

Inventions X and XXXIV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination can use a nucleic acid sequence encoding an amino acid sequence of at least 80% when compared to a polypeptide consisting of SEQ ID NO: 2 or a polypeptide consisting of SEQ ID NO: 2. The subcombination has separate utility such as a method for evaluating at least one compound for its ability to modulate calcium homeostasis.

The reasons set forth above applies to each subcombination set forth in groups XI-XVII and their corresponding combination as set forth in groups XXXIV-XXXXI.

Inventions XXXXVII and XXXXVI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination can use any isolated nucleic acid encoding a toxic insect ion

channel. The subcombination has separate utility such as expressing an isolated nucleic acid encoding a toxic insect ion channel in either an in vitro or an in vivo host cell.

In addition, if applicants elect Group XXXII, the following additional restriction is required.

Sequence Election Requirement Applicable to Group XXXII

In addition, Group XXXII detailed above reads on patentably distinct combination of sequences. Each combination is patentably distinct because they comprise a group of unrelated sequences, and a further restriction is applied to the Group. For the elected Group, Applicants must further elect a single combination nucleotide sequence. For example, Applicants must elect a single combination (*i.e., 2, 20, 25 polypeptide sequences*) of polypeptide sequences and identify the SEQ ID NOs of the combination in the claims.

The restriction practice of Group XXXII is provided by MPEP 803.04, example (c), wherein the section states:

"Applications containing only composition claims reciting different combination of individual nucleotide sequences...*will be* subject to a restriction requirement. Applicants *will be* required to select *one combination* for examination. If the selected combination contains *ten or fewer sequences, all of the sequences of the combination will be searched*. If the selected combination contains more than ten sequences, the combination will be examined following the procedures set forth above for example (B)"

Example (B) states that the presence of one novel and non-obvious sequence within the combination will render the entire combination free of prior art (MPEP 803.04).

Therefore, Applicants must elect a ***single combination*** of polynucleotide (or gene) sequences to which the claimed combination comprises. Further, Applicants are advised to identify up to Ten (10) polynucleotide sequences (or genes) (within the combination) which are least likely to be found in the prior art, for the examination to be facilitated.

If applicants elect Group XXXIII, the following additional restriction is required.

Sequence Election Requirement Applicable to Group XXXIII

In addition, Group XXXIII detailed above reads on patentably distinct combination of sequences. Each combination is patentably distinct because they comprise a group of unrelated sequences, and a further restriction is applied to the Group. For the elected Group, Applicants must further elect a single combination nucleotide sequence. For example, Applicants must elect a single combination (*i.e., SEQ ID NO: 63 and 64*) of insect ion channel and identify the SEQ ID NOs of the combination in the claims.

The restriction practice of Group XXXIII is provided by MPEP 803.04, example (c), wherein the section states:

"Applications containing only composition claims reciting different combination of individual nucleotide sequences...*will be* subject to a restriction requirement. Applicants *will be* required to select *one combination* for examination. If the selected combination contains *ten or fewer sequences, all of the sequences of the combination will be searched*. If the selected combination contains more than ten sequences, the combination will be examined following the procedures set forth above for example (B)"

Example (B) states that the presence of one novel and non-obvious sequence within the combination will render the entire combination free of prior art (MPEP 803.04).

Therefore, Applicants must elect a ***single combination*** of polynucleotide (or gene) sequences to which the claimed combination comprises. Further, Applicants are advised to identify up to Ten (10) polynucleotide sequences (or genes) (within the combination) which are least likely to be found in the prior art, for the examination to be facilitated.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re*

Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, acting SPE – Art Unit 1635, can be reached at (571) 272-0811.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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Brian Whiteman
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